

rules to calculate the price of branded drugs. Typically there is no negotiation between manufacturers and the IPR body. In the context of the German AMNOG price negotiations and the role of Germany as a key reference country, there is dearth of evidence on the international impact of the AMNOG law. Our objective was to evaluate the potential impact. **METHODS:** An IRP tool (Orange) was used to simulate scenarios of price agreements for a new branded drug between the German Head Association of the Statutory Health Insurance Companies and the manufacturer. The impact of the price agreement on other countries was evaluated based on the existing IRP rules as defined in the Orange tool. All prices were initially set at 100 euro to limit the impact to Germany only. **RESULTS:** A 50% price drop in Germany, for example, would lead to a range of reductions across the world. The largest impact in Europe would be in France, Romania, Russia, Slovenia and Luxembourg (50% decrease) followed by Norway, Greece (17%) and the Netherlands (13%). Switzerland, Ireland, Denmark and Austria would be only marginally impacted. In contrast, with a price increase in Germany of 25% a limited impact in other countries was observed. Such an increase would lead to 6% price rise in the Netherlands, 4% in Switzerland, 3% in Ireland and Denmark, and a 1% increase in Austria. **CONCLUSIONS:** Price negotiations in Germany could potentially impact the price of new branded therapies in numerous other countries. Ongoing downward pressure on pharmaceutical prices could ultimately have a negative impact on innovation and drug development in Europe.

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ULTRA ORPHAN AND CANCER DRUG PRICING TRENDS IN THE US AND THE UK

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OBJECTIVES: Both ultra orphan and cancer drugs are premium priced therapies with high annual per patient costs. The local legislation and reimbursement mechanisms have had significant impact on pricing trends for these therapies. The objectives of this analysis were to compare the price differential for ultra orphan and cancer drugs in the US and the UK, and understand the impact of local reimbursement mechanisms. **METHODS:** A set of 22 drugs (10 ultra orphan and 12 cancer drugs) was selected based on their availability in the US and the UK. The 2014 AWP, WAC and net prices were obtained for all 22 drugs. All UK prices were converted to USD. Primary discussions with ex-payer and policy experts were conducted to understand the basis and implication of the price differentials. **RESULTS:** For ten selected ultra orphan drugs, the median WAC price premium for the US compared to the UK net price was 10%. For 12 selected cancer drugs the median WAC price premium for the US compared to the UK net price was 106% (based on AWP the premiums were 29% and 149%, respectively). Eight out of 10 ultra orphan and 12 out of 12 cancer drugs were higher priced in the US compared to the UK. Primary discussions with experts suggest the role of legislation for coverage of cancer drugs in the US and special coverage of rare disease products in the UK and reimbursement mechanisms (use of cost effectiveness driven HTAs in the UK and the use of co-pay in the US) as primary drivers of high price differential for cancer drugs versus ultra orphan therapies. **CONCLUSIONS:** The local reimbursement mechanisms are major drivers of price differential for ultra orphan and cancer drugs in the US and the UK.

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DISCOUNT DISTRIBUTION ANALYSIS OF ORIGINAL MEDICINES WHICH HAS NO GENERICS IN TURKEY

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OBJECTIVES: Pharmaceutical industry continues to grow and drug prices are a burden for countries. Reference price system is assumed that such a practice concerning medicines will lead to a decrease in medicine expenditures as medicine prices decrease. The objectives of this analysis to determine the distribution of discount of original medicines which has no generics from the reimbursement agency perspective in Turkey. **METHODS:** In the analysis, "Detailed Price List" data published on the website of the Ministry of Health's Turkish Medicines and Medical Devices Agency (TMMDA) and "Annex 4-A Funded Medicines List" data published by Social Security Institution (SSI) were used. The lists were merged using the Excel software and generic medicine including genericized original medicines with different pricing and payment conditions compared to original medicines with no generics and other specific medicines such as blood products, enteral nutrition products, etc. and specific conditions such as medicines with no reimbursement were excluded. The analysis was made with a total of 568 original medicines with no generic. Ex-factory prices were used in the analysis. The reference prices of all original medicines (100%) are calculated by multiplying their actual reference price values with the periodic Euro value in the price list used in Turkey. **RESULTS:** A comparison between ex-factory prices in TL and actual reference prices in TL revealed that 42.6% of the medicines had the same price, while 57.4% had a different price. The distribution of discount rates applied by SSI for 370 original medicines with a 41% discount rate and 99 original medicines with a 32.5% discount rate were found. **CONCLUSIONS:** In this analysis the mandatory discount rate for original drugs of 41% discount is mostly implemented by SSI. In rare cases, higher or lower discount rate can be applied. This is compatible with the implementation of the original drug reimbursement policy rules. However, further analysis should be done to obtaining more detailed information.

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IMPACT OF ASSESSMENTS OF NEW MEDICINES BY THE SMC IN ENGLAND

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OBJECTIVES: The Scottish Medicines Consortium (SMC), unlike the National Institute for Health and Care Excellence in England, assesses all new medicines.

It is often assumed that the assessment by the SMC influences subsequent local recommendations on the funding and use of medicines in England. This research tests that hypothesis. **METHODS:** Research was based on 86 medicines assessed by the SMC in 2012 and 2013, of which 56 were not reviewed by NICE. A sample of five local assessment groups in England was identified. From these we found a total of 53 recommendations relating to medicines not reviewed by NICE, of which 27 were published subsequent to the SMC assessment. **RESULTS:** Only around half (51%) of local assessments in England were published subsequent to SMC assessments, so could potentially have been influenced. Of these recommendations two-thirds (18) were consistent with the SMC verdict, and one third (9) differed. Detailed analysis revealed additional factors. Several of the medicines in the sample were recommended by NICE on the basis of evidence summaries or in clinical guidelines. This advice, although not mandatory, appears from our sample to have been followed. Also some medicines not recommended by SMC were subject to specialised commissioning, the responsibility of NHS England rather than local commissioners. **CONCLUSIONS:** There is some consistency between assessments of new medicines in Scotland and England (as might be expected given that the evidence and decision criteria are broadly similar) but there are also significant differences. It appears English advisory bodies make their decisions independently of SMC recommendations, and often earlier. Other differences, such as NICE evidence summaries and Specialised Commissioning in England, further reduce the influence of Scottish decisions.

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REGULATIONS OF THE GERMAN DRUG MARKET

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OBJECTIVES: The framework specifications on pharmaceuticals (Rahmenvorgaben Arzneimittel) by the National Association of Statutory Health Insurance-Accredited Physicians (KBV) and the Statutory Health Insurance Scheme (GKV-Spitzenverband) are annually redefined. These specifications (Rahmenvorgaben) are binding for the 17 subnational drug agreements (Arzneimittelvereinbarungen) and target agreements (Zielvereinbarungen). They include quotas for lead compounds and prescription quotas. Individual subnational districts (KV Gebiete) set local drug specifications and quotas. These guide the prescription behavior. The objective of the analysis is to identify differences between the subnational regions regarding target agreements and resulting impacts. The analysis focuses also on the shift from innovative biologics to biosimilar products. **METHODS:** The 17 subnational drug target agreements (Zielvereinbarungen) are analyzed regarding their differences/specialties and their regulatory effect on the prescription of pharmaceutical classes e.g. anti-diabetic, anti-hypertensives, and the biosimilar proportion. Additionally the rapid prescription information of the SHI (GKV-Arzneimittel-Schnellinformation = GAmSi-data) and local regulation instruments are reviewed. **RESULTS:** The 17 target agreements (Zielvereinbarungen) for the 15 defined classes of pharmaceuticals result in different quota fulfillment. An example is erythropoietin with a quantitative quota range from 20% to 63%. The qualitative regulatory actions regarding the switch of biologics (Erythropoietin, Somatropin, Filgrastim, TNF alpha-blocker) to biosimilars vary from no regulation to recommendation or even priority prescription. The additional defined subnational target agreements (Zielvereinbarungen) include targets on diabetes test strips, biosimilar quotas, individual substances or product-classes and can be individually adapted for the different physician specialties. **CONCLUSIONS:** In addition to the federal regulation system the German pharmaceutical market is fragmented in 17 subnational areas leading to different treatment behavior depending on the relevant subnational target agreements and the defined quotas. This analysis shows the wide variety of the subnational target agreements for different drug classes. They are not uniform and on a qualitative basis they even can exceed the determined federal targets.

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A SYSTEMATIC COMPARISON OF IQWiG RECOMMENDATIONS AND G-BA DECISIONS IN THE AMNOG PROCESS IN GERMANY

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OBJECTIVES: Since the introduction of AMNOG more than 100 IQWiG recommendations and G-BA decisions on the early benefit assessment have been published. In various assessments, the IQWiG recommendation and the related G-BA decision differ in terms of argumentation and result. In this study, these differences were systematically analyzed in order to draw conclusions for further proceedings. **METHODS:** Data of all published IQWiG recommendations and G-BA decisions were standardized and transferred into the Prismaccess database. In a systematic analysis, major differences between the recommendations and decisions were quantitatively assessed. All documents of the identified decisions where differences were observed were then compared qualitatively. **RESULTS:** In several aspects, major differences were found between IQWiG recommendations and G-BA decisions in approximately 25% of all cases. On the subgroup level, it was observed in at least n=10 cases that the G-BA tends to use a broader definition of subgroups in its decisions than used in the IQWiG dossiers, (e.g. Telaprevir). In terms of the extent of the additional benefit, 17 differences between IQWiG and G-BA decisions were registered, while mostly G-BA tend to evaluate better than IQWiG. In the probability of the additional benefit also some differences were observed. This can be explained by the opportunity to provide additional/new evidence during the oral hearing, which may influence the decision positively. Some proceedings were identified that took another way, as intended by the legislature: for example with Cobicistat, an incomplete paperwork was handed in, to achieve at least the price of the ACT. Still accepted by the G-BA, it is obvious that this should not be the normal case. **CONCLUSIONS:** In an early stage, G-BA consultations might be helpful clarifying subgroups-requirements. In the process, the oral hearing was identified as important instrument to supplement the required data and to correct uncertain issues from the dossier.